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09/486,613	02/29/2000	DEBORAH C. MASH	N08-002	8931

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/486,613

Applicant(s)

MASH, DEBORAH C.

Examiner

Abigail M. Cotton

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2006 and 26 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-9 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/24/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This office action is in response to the amendment submitted on June 9, 2006. Claims 6-9 and 25-30 are pending in the application and are being examined on the merits herein.

The rejection of claims 25-30 under 35 U.S.C. 103(a) over U.S. Patent No. 5,925,634 to John Olney, issued July 20, 1999, in view of the article by Mash et al, 1995, as set forth in the Office Action mailed January 13, 2006, is being withdrawn in view of Applicant's amendments to the claims. In particular, Applicant's have amended the claims to recite that the method is for treating a patient to alleviate nociceptive pain, whereas the teachings of Olney are directed to the treatment of neuropathic pain using NMDA receptor agonists. Applicants have presented evidence in the declaration filed December 22, 2005, showing that neuropathic pain is recognized as a class of pain that is distinct from nociceptive pain. For example, while opioid agonists are known to be useful in the treatment of nociceptive pain, neuropathic pain is mediated through NMDA receptors and does not conventionally respond to opiates (see paragraph 28 of Declaration, in particular.) Applicants have also cited art that distinguishes between neuropathic and nociceptive pain and conventional treatments therefore (see, e.g., the article entitled "Neuropathic Pain in Cancer Patients: Mechanisms, Syndromes and Clinical Controversies," by Martin et al, 1997, the Journal of Pain and Symptom Management, of record, et al.) Support for the alleviation of "nociceptive pain" is found

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on page 9, final full paragraph of the instant specification, which discloses that noribogaine is an “antinociceptive agent.” Accordingly, one of ordinary skill in the art at the time the invention was made would not have found it obvious to apply the method of Olney and Mash et al. to the treatment of nociceptive pain, as the references do not teach or suggest providing the compound for the treatment of pain other than neuropathic pain.

The rejection of the claims over Lotsoff, Pablo et al, Mash et al, Archer, and Applicant’s own admission as to the state of the prior art, are being withdrawn in view of Applicant’s amendments to the claims. In particular, as the references are directed to the treatment of drug withdrawal, and the pain inherently associated therewith, the references do not provide any motivation to treat pain that is in the absence of withdrawal symptoms, as recited in the claims.

### ***Priority***

The Examiner wishes to state for the purposes of the record that claims 6-9 and 25-30 do not receive benefit of the priority date of the provisional application 60/057,921 filed September 4, 2006, because the provisional application does not provide sufficient support for the invention as instantly claimed. For example, the provisional application does not provide support for the limitation that the treatment is in “the absence of withdrawal symptoms associated with drug dependency” as recited in claims 6 and 25,

and does not provide support for concomitantly administering systemically to said patient an opioid antagonist, as recited in claim 6. Accordingly, the effective filing date of the instant claims 6-9 and 25-30 corresponds to the filing date of the PCT application from which the application is derived of September 3, 1998.

### ***Claim Objections***

Claims 27 and 28 are objected to due to a typo-type error. In particular, the claims recite "the method of 25," instead of "the method of claim 25". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification does not provide adequate support a method of treating a patient to alleviate nociceptive pain

"in the absence of withdrawal symptoms associated with drug dependency," as recited in claims 6 and 25. The specification teaches for example, that noribogaine can be administered "either for the treatment of pain or for the treatment of drug dependency or abuse" (see page 8, first full paragraph, in particular), but does not specifically teach that the drug is administered to treat nociceptive pain in the absence of withdrawal symptoms associated with drug dependency, as recited in the instant claims. Accordingly, the amendment to the claims constitutes new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Modulation of Morphine-Induced Antinociception by Ibogaine and Noribogaine" by Bagal et al, 1996, Brain Research, 741, pages 258-262 (of record.)

Bagal et al. teaches that co-administration of noribogaine and morphine resulted in an increase in morphine antinociception (see abstract, in particular.) Bagal et al. teaches the opiates such as morphine are administered to provide analgesia (see page

258, in particular.) Thus, Bagal et al. teaches that morphine is an antinociceptive agent, and thus is capable of alleviating antinociceptive pain, as recited in claim 25.

Bagal et al. does not specifically teach administering noribogaine to treat pain in the absence of withdrawal symptoms associated with opiate drug dependency, as recited in claim 25. However, as Bagal et al. teaches that morphine generally provides analgesia and pain relief, and also teaches that noribogaine increases the antinociceptive activities of morphine, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide noribogaine with morphine to treat pain, including pain that is in the absence of withdrawal symptoms, with the expectation of providing improved pain relief.

Regarding claim 25, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase “consisting essentially of” is being construed as equivalent to “comprising,” absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase “consisting essentially of.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding the recitation that the method is performed “without addiction” as recited in claim 25, it is considered that as the prior art renders obvious performing the

same method steps with the same composition as claimed, the method would necessarily also result in treatment without addiction, as instantly recited.

Regarding claims 27-30, Bagal et al. et al. teaches that noribogaine can be provided in an amount of 40 mg/kg, which meets and/or is close to the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of noribogaine provided in the composition, according to the guidance provided by Bagal et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, claims 25 and 27-30 are obvious over the teachings of Bagal et al.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Modulation of Morphine-Induced Antinociception by Ibogaine and Noribogaine" by Bagal et al, 1996, Brain Research, 741, pages 258-262 (of record), in view of U.S. Patent No. 5,580,876 to Crain et al, issued December 3, 1996.



Bagal et al. is applied as discussed for claims 25 and 27-30 above, and renders obvious a method of alleviating nociceptive pain in the absence of withdrawal by administering noribogaine along with morphine.

Bagal et al. does not specifically teach concomitantly administering an opioid antagonist with the noribogaine, as recited in claim 6.

Crain et al. teaches that an opioid receptor antagonist, such as naltrexone or naloxone, can be administered in combination with an opioid agonist, such as morphine, to enhance the degree of analgesia (see column 1, lines 40-50, and column 4, lines 25-65, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the opioid antagonist of Crain et al. in the morphine and noribogaine treatment method of Bagal et al, because Bagal et al. teaches providing morphine and noribogaine for the treatment of pain, and Crain et al. teaches that opioid antagonists enhance the pain relieving activity of opioid agonists such as morphine. Thus, one of ordinary skill in the art would have been motivated to concomitantly administer the opioid antagonists with morphine and noribogaine with the expectation of providing improved pain treatment. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very

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same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding claims 7-8, Crain et al. teaches that the opioid antagonist can be naloxone or naltrexone, as discussed above, and provides examples of having amounts of the antagonists that may be suitable (see Examples 1-8, in particular), while Bagal et al. teaches amount of noribogaine that may be suitable, as discussed above. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of noribogaine and/or opioid antagonist provided in the composition, according to the guidance provided by Bagal et al. and Crain et al, to provide a composition having desired properties, such as desired pain relief. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 9, Crain et al. teaches that the administration of such compositions can be transdermal.

Claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Noribogaine Stimulates Naloxone-Sensitive [<sup>35</sup>S]GTP<sub>γ</sub>S Binding" by

Pablo et al, having a website publication date of December 20, 1997 (see copy of publication as newly provided), NeuroReport, 9, pages 109-114, 1998, in view of the article entitled "k-Opioid Receptors and Analgesia" by Mark. J. Millan, Trends in Pharmacological Sciences, 1990, vol. 11, pages 70-76.

Pablo et al. teaches that it has been discovered that noribogaine is a full agonist at the  $\mu$ -opioid receptor having an intrinsic activity comparable to the full agonist morphine (see abstract, in particular.)

Pablo et al. does not specifically teach administering noribogaine to treat a patient to alleviate nociceptive pain in the absence of withdrawal symptoms associated with drug dependency, as recited in claim 25.

Millan teaches that opioids such as morphine are analgesics having antinociceptive activity (see abstract and second full paragraph of page 70, in particular.) Millan further teaches that agonists at  $\mu$ -opioid receptors are powerful analgesics (see page 72, right hand column third full paragraph, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide analgesia, or nociceptive pain relief with a  $\mu$ -opioid receptor agonist as taught by Millan with the specific agonist that is noribogaine, as taught by Pablo et al, because Pablo et al. teaches that noribogaine is a  $\mu$ -opioid

receptor agonist, and Millan teaches that such agonists provide nociceptive pain relief in general, which includes pain that is in the absence of withdrawal symptoms. Thus, one of ordinary skill in the art would have found it obvious to provide the noribogaine of Pablo et al. in a method of pain relief, as taught by Millan, with the expectation of providing a  $\mu$ -opioid receptor agonist suitable for pain relief.

Regarding claim 25, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding the recitation that the method is performed "without addiction" as recited in claim 25, it is considered that as the prior art renders obvious performing the same method steps with the same composition as claimed, the method would necessarily also result in treatment without addiction, as instantly recited.

Regarding claim 26, it is noted that Pablo et al. teaches that noribogaine by itself is an agonist of the  $\mu$ -opioid receptor, and thus one of ordinary skill in the art would have been motivated to provide the noribogaine as the sole analgesic agent with the expectation of providing the pain relief.

Regarding claims 27-30, Pablo et al. generally teaches the affinity of the noribogaine to the opioid receptor (see Results, in particular.) Furthermore, Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of noribogaine provided in the composition, according to the guidance provided by Pablo et al, to provide a composition having desired properties, such as desired pain relief. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Noribogaine Stimulates Naloxone-Sensitive [<sup>35</sup>S]GTP<sub>γ</sub>S Binding" by Pablo et al, having a website publication date of December 20, 1997 (see copy of publication as newly provided), NeuroReport, 9, pages 109-114, 1998, in view of the article entitled "k-Opioid Receptors and Analgesia" by Mark. J. Millan, Trends in Pharmacological Sciences, 1990, vol. 11, pages 70-76, and further in view of U.S. Patent No. 5,580,876 to Crain et al, issued December 3, 1996.

Pablo et al. and Millan are applied as discussed above, and render obvious a method of alleviating nociceptive pain in the absence of withdrawal by administering

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noribogaine. Pablo et al. and Millan also teach that noribogaine is a  $\mu$ -opioid receptor agonist, as is morphine.

The references do not specifically teach concomitantly administering an opioid antagonist with the noribogaine, as recited in claim 6.

Crain et al. teaches that an opioid receptor antagonist, such as naltrexone or naloxone, can be administered in combination with an opioid agonist, such as morphine, to enhance the degree of analgesia (see column 1, lines 40-50, and column 4, lines 25-65, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the opioid antagonist of Crain et al. in the noribogaine treatment method of Pablo et al. and Millan, because Pablo et al. and Millan teaches providing noribogaine for the treatment of pain, and teach that noribogaine is an opioid agonist just like morphine, and Crain et al. teaches that opioid antagonists enhance the pain relieving activity of opioid agonists such as morphine. Thus, one of ordinary skill in the art would have been motivated to concomitantly administer the opioid antagonists of Crain et al. with noribogaine agonist as taught by Pablo et al. and Millan with the expectation of providing improved pain treatment. Note it is considered that "[l]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding claims 7-8, Crain et al. teaches that the opioid antagonist can be naloxone or naltrexone, as discussed above, and provides examples of having amounts of the antagonists that may be suitable (see Examples 1-8, in particular), while Pablo et al. and Millan suggest amounts of noribogaine that may be suitable, as discussed above. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of noribogaine and/or opioid antagonist provided in the composition, according to the guidance provided by Pablo et al, Millan and Crain et al, to provide a composition having desired properties, such as desired pain relief. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 9, Crain et al. teaches that the administration of such compositions can be transdermal.

***Allowable Subject Matter***

The Examiner notes that if (1) the rejection under 35 U.S.C. 112, first paragraph for new matter, and (2) the rejection under 35 U.S.C. 103(a) over Pablo in view of Millan, were overcome, then claim 26 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Accordingly, the Examiner respectfully suggests the following claim amendments to overcome the rejection of claim 25 over 35 U.S.C. 112, first paragraph and over Bagal et al. which incorporate the limitations of dependent claim 26:

25. A method of treating a patient to alleviate nociceptive pain in the absence of the treatment of drug dependency or drug abuse ~~in the absence of withdrawal symptoms associated with opiate drug dependency with an opioid agonist without addiction,~~ comprising:

administering systemically to said patient a pharmaceutical composition consisting essentially of an effective amount of noribogaine or its pharmaceutically acceptable salt ~~to said patient effective~~ to reduce or eliminate said nociceptive pain in said patient, wherein the noribogaine or its salt is the sole analgesic agent in said pharmaceutical composition.



The amendments to the preamble as proposed by the Examiner are supported in the instant specification on page 8, lines 5-20, which disclose that the noribogaine can be administered "either for the treatment of pain or for the treatment of drug dependency or abuse," and thus positively recites the treatment of either pain, as in the proposed claim, or drug dependency or abuse, as is excluded from the proposed claim. According to MPEP 2173.05 "any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recite in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977.)" Thus, the proposed amendment would overcome the rejection under 35 U.S.C. 112, first paragraph, for new matter.

The proposed amendment would also overcome the rejections over Bagal et al. because Bagal only teaches that the noribogaine is provided in combination with morphine, an analgesic, to improve the antinociceptive activity of the morphine. Bagal et al. does not teach or suggest that noribogaine has analgesic properties itself or would be otherwise capable of providing pain relief in the absence of any other analgesic such as morphine. Thus, one of ordinary skill in the art at the time the invention was made would not have had any motivation, based on the teachings of Bagal et al, to provide the noribogaine as the sole analgesic agent for the treatment of nociceptive pain, and in the absence of the treatment of drug dependency or drug abuse.

The Examiner notes that the proposed amendments do not overcome the rejection over Pablo et al. in view of Millan, as Pablo et al. discloses the discovery that noribogaine is an agonist at an opioid receptor, which agonists are known to treat nociceptive pain as taught by Millan. The Pablo et al. reference is co-authored by the instant inventor, and qualifies as a reference only under the provisions of 35 U.S.C. 102(a). The Examiner respectfully advises Applicants to review section 706.02(b) of the MPEP to evaluate the suitability of the means listed therein for overcoming rejections for references that qualify as art under the provisions of 35 U.S.C. 102(a).

In a telephone conversation on June 14, 2006, Applicant's representative, Mr. Henry Coleman, proposed an alternative to the Examiner-suggested amendment to claim 25. In particular, Mr. Coleman suggested alternatively amending the claim to recite "wherein the noribogaine is administered in the absence of any concomitant opioid analgesic therapy," which phrase appears in Applicant's specification on page 3, lines 15-16. However, the Examiner notes that the entire sentence to which Applicants refer further recites that "in patients for whom opioid analgesics are contraindicated, noribogaine is administered systemically in an amount effective to reduce or eliminate pain in the absence of any concomitant opioid analgesic therapy," (underline added) and thus the teaching of the absence of concomitant opioid analgesic therapy appears to specifically apply only to that population of patients for whom opioid analgesics are contraindicated. The claims at present are not limited to the treatment of only those patients for whom opioid analgesics are contraindicated, and thus Applicant's are

advised that such an amendment may raise the question of new matter. Should Applicants wish to pursue such an amendment, the Examiner respectfully advises Applicants to provide arguments that are sufficient to show why such an amendment would not constitute new matter, and/or amend the claims in such a manner that no new matter is introduced.

### ***Response to Arguments***

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new ground(s) of rejection.

The Examiner notes that Applicant's assert that the Pablo et al. reference does not qualify as prior art against the instant invention. In particular, Applicant's claim priority back to the filing date of the provisional application, and assert that as the Pablo et al. reference was published after this provisional filing date, the reference does not qualify as prior art. However, the Examiner notes that the instant claims are not fully supported by the provisional application as filed, and thus do not receive benefit of the provisional application filing date, as discussed above. Thus, the Pablo et al. reference, as published on the web on December 20, 1997, qualifies as prior art against the instant claims at least under the provisions of 35 U.S.C. 102(a), as the article was published before the effective filing date (the PCT filing date) of the instant application.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', is written over a horizontal line.

**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**